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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,164	08/30/2006	Naoki Nagahara	2006_1328A	6045

513 7590 11/30/2011

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EXAMINER	
DICKINSON, PAUL W	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
11/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/591,164	NAGAHARA ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 September 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-6,12-14 and 18-24* is/are pending in the application.

5a) Of the above claim(s) *3,6 and 13* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1, 4-5, 12, 14, and 18-24* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, filed 9/16/2011, have been fully considered but they are not deemed to be fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The rejection of claims 1, 4-5, 12, 14, and 18-24 under 35 U.S.C. 103(a) as being unpatentable over US 20050181052 ('052) in view of US 6887307 ('307) is maintained.

Applicant argues the following points:

(1) The pullulan capsule of '307 are special pullulan capsules, whereas the pullulan capsules of the instant invention are common.

(2) Lansoprazole taught by '052 is unstable to acids, where '307 requires use of acidic surfactants in the setting system. Therefore one would not modify the capsule of '052 containing lansoprazole with the pullulan capsule of '307.

(3) The amended claims are to at least two solid preparations having different medicine release properties, which is not taught or suggested by '052 or '307.

Applicant's arguments have been fully considered but are not found persuasive.

Regarding (1), the pullulan capsules of the instant claims and the pullulan capsules of '307 are related as genus/species. Although the pullulan capsules of '307 are made with a specific setting system, they are made of pullulan and are therefore pullulan capsules. The pullulan capsules of '307 are an embodiment, a species, of the instant pullulan capsules.

Regarding (2), although acidic sequestering agents are taught by '307, this is an optional embodiment of the invention. The ordinary artisan would understand, when encapsulating acid sensitive drugs, such as lansoprazole, to exclude optional acids from the capsule.

Regarding (3), the limitation in claim 1 requiring at least two solid preparations, the only distinguishing characteristic between the "at least two solid preparations" is that they have "different medicine release properties". In a given granule formulation where microtablets are coated with an enteric coating, such as the microtablets made in Example 1 of '052, each particle in the formulation will have a slightly different radius and a slightly different amount of enteric coating. The particles in '052 are made by milling, and in this method of making each particle will have a slightly different radius, and upon coating, each particle will have a slightly different amount of enteric coating. The slight difference in radius and amount of enteric coating will give rise to a slightly different release profile from particle to particle. This difference will be small, but there

will be a difference. As the only distinguishing characteristic between the "at least two solid preparations" in claim 1 is that they have "different medicine release properties", the Examiner submits that the enteric coated particles of '052, although made in a single batch, meet this requirement, because all of the particles provide a slightly different release profile. For the sake of argument, even if all the particles in the preparation of '052 have identical release profiles, this limitation in claim 1 still does not distinguish Applicant's invention over '052, because it is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). It would have been obvious to add two separately made particle formulations of '052 to a single capsule, to produce a third composition useful for the same purpose, i.e. treatment of gastrointestinal diseases ('052: paragraph 64). For example, it would have been obvious to prepare one particle preparation with a particular enteric polymer (such as cross-linked polyvinyl pyrrolidione, taken from paragraph 19 of '052), another particle preparation with a different enteric polymer (such as hydroxypropylmethyl cellulose phthalate, taken from paragraph 19 of '052), and add the two particle preparations to a single capsule, to create a formulation for treating gastrointestinal diseases. Preparing single formulations that are made up of different release profiles of the same drug is a common tool in the art to provide varied release of the drug. In the instant case, the expectation of success is high, as '052 teaches that a combination of enteric coatings may be used (paragraph 19).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

November 26, 2011